

## REMARKS

This Amendment is responsive to the Office Action dated September 14, 2010, and telephone interview of October 13, 2010.

Claims 3, 6, 7, 9, 11, 12, 14-17, 19, 22 and 23 have been amended. Claims 3-9, 11-17, 19-28, 30 and 38-40 remain pending in the application. Applicant respectfully requests reconsideration of the Examiner's rejections.

Applicant will file a Terminal Disclaimer to overcome the provisional obviousness-type double patent rejection, if necessary. The claims have been amended to overcome all of the Examiner's objections and Section 112 rejections.

The remaining rejections pertain to the Examiner's citation of U.S. Patent No. 6,790,178 to Mault ("Mault '178") under Section 102 against Applicant's pending claims. For the reasons provided at great length below, Applicant respectfully traverses such rejection.

## ARGUMENT

Examiner cites **Mault '178; Col.4.II; 54-56 "In this embodiment, when the PDA and monitor module are docked, they form an integral unit."** In the Office Action, the Examiner interprets the act of docking the PDA and module as being the action that makes Mault's monitor/module and PDA a common-housing device. It also appears that the Examiner considers the act of insertion or plugging the monitor/modules into the PDA is the equivalent of the PDA being docked and this constitutes a common housing. Applicant however notes that Mault teaches that the act of insertion or plug-in of the monitor module into the PDA is not a permanent requirement by Mault. (See **Mault '178, col 5, ll. 23-25. "Alternatively, the physiological monitor may be operational without being interconnected or in communication with a PDA."** Clearly, if the monitor module and PDA are not interconnected or in communication as described above, they cannot be integral or share a common housing at all times.

Where Mault does temporarily connect the monitor/module to the PDA, it is limited to when the user chooses to use this particular embodiment and only on those occasions deemed by

the user. This becomes obvious as Mault teaches that the module can be used on its own exemplifying Mault's teachings of distributed components. **Mault col.7.11;1-3 "The person uses a pedometer module, either on its own or mated with the PDA..."** The temporary nature of the PDA and monitor/module is also clear from Mault's statement that **Col.5.11; 1-3 "When the monitor module is not in use, the PDA may be removed and use for alternative purposes, possibly with other modules."** Though, the Applicant understands that the Examiner is broadly interpreting only "one" teaching relating to "WHEN" the monitor module are docked, they form an integral unit. Allowing usage during certain situations regarding insertion/plugged-in of the PDA and components provides "no" evidence of a common housing (e.g. when the PDA is inserted/plugged-in). Under Mault's teachings, during certain embodiments these components do not interconnect, providing "no" evidence of a common housing.

"When" an integral unit is formed, as the Examiner interprets, in certain Mault scenarios, this never occurs. It would appear undebatable and impractical to consider the temporary docking of the module and PDA only under "certain conditions", as taught by Mault above, to be considered as evidence that the PDA and module are integral, or share a common housing, as this periodic connection must be regarded as a non-permanent required condition of Mault, showing additional evidence that Mault's parts are sometimes distributed. In Applicant's invention the electronic assembly parts are not distributed and are permanently contained within the housing of the medical apparatus, such that the electronic assembly and medical apparatus always share a permanent common housing. Whereas, Mault at **Col.4.11; 30-32 states "The PDA need not be a unitary device, but instead the components could be distributed."** There are no special conditions regarding additional distributed parts that must be inserted or plugged-in, required to make the Applicant's invention integral, "when" used, as the Applicant's novel invention always has a permanent common-housing. This fact substantially differentiates Mault's invention from Applicant's claimed invention.

Applicant also notes that Applicant's claimed invention states that the electronic assembly is permanently contained within the housing of the medical apparatus. *The Examiner's Office Action specifically indicated that "the Examiner interprets the PDA as a self-contained*

*electronic assembly." Page 6 of the Office Action. "As the physiological monitor is inserted within the slot of the PDA", the Examiner is relying on the PDA's housing for the common housing. Applicant is claiming the housing of the medical apparatus is not the electronic assembly, rather the medical apparatus is only the structure of the housing in which the electronic assembly is directly contained and connected at all times. Thus, the housing in Mault relied on by the Examiner and Applicant's medical apparatus housing are different and not the same.*

In another unarguable example, the gauge of the Applicant's traditional medical device, within the housing of the medical device itself, such as, a float, a movable section or a ball, which responds to the patient's breath in order to supply measurement and data (e.g. peak flow meter or Incentive Spirometer). These examples of gauges are permanently encased within the medical device housing itself and cannot be removed or distributed under any circumstances during normal use. This data supplying part/gauge of the Applicant's invention cannot be removed, under any conditions, or it will not work as it is encapsulated within the medical apparatus itself, which makes it impossible to be removed. This is unlike Mault's monitor/module (which obtains the data), which may be distributed (i.e. plugged-in, inserted or attached by cable), and being separated from the housing. Please note that the Applicant's measuring device/data part of the housing cannot be removed under any circumstances. These parts are not distributed and are encapsulated within the medical device itself, making it impossible to perform the same function as Mault's monitor module which are distributed and are not encapsulated in Mault's device. The applicant's medical data obtaining component/gauge within the medical device itself, is a "true" common housed medical device and cannot be removed, taken out, inserted, plugged-in, or attached by a cable in any scenario. Thus, these unchangeable conditions of the data supplying component of the Applicant's medical device show indisputable differences between Mault's invention and Applicant's.

Since Applicant's electronic assembly is solely contained within the medical apparatus housing itself, and the medical apparatus and the electronic assembly permanently share the same power source, it is obvious that the power source is not distributed as taught by Mault. See

**Mault col.4.11 29-32 “The PDA need not be a unitary device, but instead the components could be distributed.”** Applicant will expand on these arguments below, but it is respectfully believed that the above arguments should be considered as sufficient on their own, to show that Mault fails to disclose the module and PDA having a common housing.

There was some confusion as to why the Examiner cited **Mault ‘178 col. 4, 11. 56 (“module may insert into an accessory slot in the PDA, or grip its housing or interconnect in any other way”)**, since the quote was different in col.4.11; 56 as specified by Examiner and cited in the Office Action rejection **col 4, 11. 56** states **“plug-in type biological sensor, e.g. metabolism, weight body temperature etc.”** However, the Applicant will use the Examiner’s citations (whether correct or incorrect), to provide further evidence of the differences between Mault and Applicant as after extensive researching of both Mault and Applicant it is obvious that they are distinctively different.

Please note that the Office Action failed to address that Applicant claims state that the electronic assembly is in communication with the “gauge” of the medical apparatus. This point has particular importance to structural and functional differences between Applicant and Mault. The Examiner, at Page 5 of the Office Action, acknowledges that Mault teaches **“a physiological monitor comprised of a computing device, e.g. PDA, and a plug-in type biological sensor, e.g. metabolism, weight body temperature etc.”** It is well known, that “physiological monitors” deal solely with living organisms (i.e. human beings). **See Mault ‘178 col 1, 11 65-67: “Physiological monitors of various types are used in the health and medical fields to monitor various physiological parameters of human patients.”** It is known that physiological monitors cannot provide data from any other elements that are not physiological such as; a cylindrical float or a ball within many traditional apparatuses (i.e. incentive spirometer), mercury moving within a glass tube (i.e. a thermometer), gauges of many varieties (i.e. oxygen tank gauge, anesthesia gauge, traditional circular pressure gauges), or any traditional mechanical gauges that are made of non-living elements (e.g. polymer, medical grade plastics, or metallic elements). Mault’s physiological/PDA system solely works with living organisms (i.e. human beings), and not with gauges as claimed by Applicant.

It is known by one skilled in art that a PDA cannot obtain or acquire any data on its own (the PDA's sole purpose is to process data). Mault's physiological monitors cannot and do not work inside a medical apparatus, which consist of essential mechanical gauged components (i.e. non-human/non-living organisms). As part of these components, many existing traditional medical apparatuses, such as those claimed by Applicant, incorporate a gauge in order to provide measurements pertaining to those gauged medical apparatuses. Mault's physiological monitors cannot and do not communicate with any traditional parts or mechanical gauges (i.e. non-living organisms). Applicant's electronic assembly is in communication with the gauge of the medical apparatus itself, as needed, in order obtain the required data. **See Applicant Page 12, line 22 through Page 13, line 9 (...Gauge 2 of Medical Apparatus 10 connects to Gauge Connector 5...)**. This data is received directly from the medical apparatus (not a living organism or even body) and the electronic assembly is within and in synthesis with the gauging elements of the medical apparatus itself See Applicant **Page 13, line 28 (...parameter measured by the Gauge 2 during the duration of time that the Apparatus 10 is used... is input to the Audio Response Unit 1...)**. With this said, please note physiological monitors are not the same as medical apparatus gauges and thus Applicant's invention is distinctively different from Mault.

Mault's system is design to "replace" traditional physiological devices with physiological monitors in the form of insertable cartridges which must make contact with the body of the user. Applicant claims a system that does "not" replace standard or traditional current medical devices but instead works within the structure of traditional medical devices in order to "enhance" the medical device itself. The Applicant's system provides and retrieves data differently than Mault's system, by being in contact with the measuring part of the traditional medical device itself. This allows the proven technology of the traditional medical apparatus that has been tested for decades to benefit from the enhancement of the Applicant's invention without any structurally change to the common housing of the device itself.

Mault also notes another difference; the PDA can be used for multiple persons. **Col 19, ll. 38-39 "... multiple persons are using the PDA..."** Applicant's invention is only used by one person during medical procedures. If multiple people are meant to use one PDA for separate module embodiments, it is also apparent that Mault's invention (i.e. PDA and Monitor/module

combination) is not claimed for any therapeutic uses, as usage for more than one person per device could transmit infectious diseases between people (i.e. touching the PDA).. Mault is silent throughout his patent concerning any therapeutic use of his invention. This is especially important not only to the Applicant, but also to the medical industry given how many therapeutic sessions are required for a patient to perform during treatment under medical care relating to a medical apparatus. Many therapeutic devices require, in a "real life" medical situation, to be used by a patient for as many as "one hundred" individual sessions per day, for weeks at a time. Mault never teaches any "repetitive" usage by the user of Mault's invention. Repetitive usage is a requirement of most therapeutic devices and this is what promotes patient/user recovery. **Applicant Page 11, ll. 1-3 "...by continually reminding the patient until the performed requirements required by that apparatus being used are met."** This therapeutic function of Applicant improved medical device is claimed throughout Applicant's application and allows the medical apparatus to remain with the patient, as medically deemed. This makes placement of the medical device always available at all times and thus reducing problems for locating the medical device. The same device is not passed around to multiple patients for obvious reasons.

Applicant's invention improves on existing medical apparatus by replacing or least significantly reducing the need for ancillary medical assistance to be present during the use of the medical apparatus by the patient. Ancillary services fall into three broad categories: diagnostic, therapeutic and custodial and are located mainly in hospitals and medical offices. The ancillary medical assistant's services, usually provided by a hospital, require the nurse who visits the patient to remind the patient to use the medical apparatus, (i.e. therapeutic, continual guidance according to the medical procedure and instructions, etc.) at all times during the day, as needed. With the Applicant's invention the improved medical device takes the place of the medical assistant allowing he/she to perform other valuable tasks, thus, saving time in areas that the ancillary medical assistant would need to previously perform. The various medical apparatuses improved upon by Applicant's invention abide by the guidelines and regulations established by governmental bodies or agencies (as is required for all medical devices), for this is what the government has stipulated for safety and regulation purposes assuring proper treatment for the patient. Applicant's electronic assembly is preprogrammed using unique Binary Codes

Voice technology within the medical apparatus itself, in accordance with the usage guidelines and regulations (i.e. FDA, AMA, etc.) for each medical apparatus so to as to comply with medical governmental guidelines.

Mault never teaches that the PDA/monitor assembly has any relationship to existing medical apparatuses or that it improves any traditional medical apparatus. Mault's PDA-monitor/module system also never makes contact with any existing standard medical device. Obviously, Mault uses the already existing PDA and physiological monitors by replacing certain limited performances relating to human beings (i.e. living organisms), and those healthcare/fitness scenarios taught by Mault. It is also obvious, through Mault's teachings, that the Mault invention is intended for use outside of a hospital (i.e. user's home), as Mault never teaches use in any hospital setting or direct patient treatment. Mault is not concerned with traditional medical apparatuses, nor improving them. Mault's invention has nothing to do with reducing or replacing ancillary medical assistance. Mault's invention, per Mault's specified functions, would not be able to be used in a hospital setting under normal regulatory governmental requirements (i.e. user must participate for set up and function for Mault's devices). See Mault **EKG/Heart sound monitor** embodiment which stipulates the use of the device as an EKG providing assembly by user. Mault's assembly would be acceptable under limited conditions (i.e. home use). It is commonly known in a hospital setting that cellphones can cause critical interference with other medical apparatuses (i.e. pacemaker and EKG machines) and thus, hospitals do not allow cell phones or PDAs to be used in the hospital due to this critical interference with other medical devices. Combining a EKG with a Heart Sound Monitor clearly shows that Mault doesn't intend his PDA and monitor module assembly for use in a hospital setting as under normal true medical EKG usage the two units are separate. Thus, Mault's invention is obviously intended to be used at home for simple healthcare/fitness program, as Mault teaches. See Mault '178 col.2.11;7-9 "**As the cost of electronic equipment (referring to physiological monitors), has fallen, lower cost physiological monitors have been used at home.**"

Mault teaches that the user is "always" required to perform the assembly and set up of the necessary parts and function of Mault's invention (i.e. record the voice instructions, enter data,

remove or attach one or more components). See Mault Col. 10 ll. 53-55 ***“In order to use the device, the user first inserts the attachment flange.”*** One or more monitor/modules must first be inserted into the PDA (i.e. dock or require user calibration). See Provisional Serial No 60/219,070 Page 11, line 19-22 ***“...the PDA may communicate with a remote device e.g. using wireless, internet connection to summons medical assistance...”***. Applicant’s invention provides an improved medical apparatus, which requires none of the above steps by the user or any alternative devices (i.e. internet or remote communication), and also eliminates the need of receiving verbal voice information (i.e. prompting, continual guidance, instructions, measurements or encouragements) from the user, or ancillary medical assistant. Applicant’s invention prompts until the patient uses the medical device ensuring compliance, thus, providing quicker recovery time. The applicant’s invention automatically generates the verbal voice information on its own, without the help of the user and without the presence of an ancillary medical assistant. Mault does not. These points show sufficient differences between Applicant and Mault.

It is noted that at the telephone interview dated October 13, 2010, it became readily apparent that the Examiner’s interpretation of Mault’s teachings, were not the same as the invention of Applicant. With this in mind, the below arguments concerning the differences between Applicant’s claimed invention and the Mault invention, for the most part, will ‘not’ rely on Applicant’s interpretations of Mault. Instead, Applicant will allow Mault’s own words to speak for themselves, to avoid any misinterpretation. To evidence the novelty and uniqueness of the invention of Applicant and the differences between Mault and Applicant’s claimed invention, Applicant will point to direct quotes from Mault and Applicant’s application, to support Applicant’s position. Using these direct quotes as precise proof, it will reveal that the respective inventions are structurally/physically different and it is the Applicant’s belief that these quotes will reverse the Examiner’s previous interpretations. Applicant and Mault are obviously not the same and Mault is not related in comparison to Applicant in any meaningful way with respect to patentability issues.



**THE EXAMINER'S OFFICE ACTION WITH MORE DETAILED  
DESCRIPTIVE ARGUMENTS AND REFERENCE CITINGS PROVIDING  
DIFFERENCES**

With the differences between Mault '178 and Applicant's invention discussed in detail above, Applicant below separates the Examiner's Office Action into sections and uses some of the key points of difference from above to address each point raised by the Examiner.

**a. THE EXAMINER CITES:**

*In regards to claims 3, 17, and 22, Mault et al. teaches a physiological monitor comprised of a computing device, e.g. PDA, and a plug-in type biological sensor, e.g. metabolism, weight body temperature etc. (col.4, 11.56). note: the Examiner interprets the PDA as a self-contained electronic assembly. Mault's PDA unit is a typical computing device equipped with processor, memory, clock, audio/visual display, power supply and software programs for various applications (see col.5, 11.19-56)."*

**Applicant's Response:**

The Applicant respectfully considers that the Examiner's interpretation, however, due to the fact that the components of the monitor (the data source), are exactly the same as the PDA (i.e. the unit that processes the data collected by the monitor), the above interpretation of the Examiner is based upon an assumption and not based upon the teachings of Mault. Mault teaches the PDA houses complex components (inherent and required), that a typical computer is not capable of performing.

The Examiner cites: **Mault #178 col.5 ll;19-56: "the monitor MAY dispense with controls, memory, processing....instead relying on the PDA to provide these functions"**. Please note the word "may". Mault is merely stating as one of the possible functions of the monitor and PDA that the monitor may dispense with certain operational components, as needed. Please read further down, in two sentences, for a more complete understanding. **See: Mault col.5.ll 23-25 "Alternatively, the physiological monitor may be operational without being interconnected or in communication with the PDA."** We see that the ability to temporarily take the processing capability as needed for the monitor is only one scenario, of allowing the

PDA to provide the monitor's functions. Mault is not claiming that the monitor always disposes and never provides the function of the components, rather as needed, the PDA can provide the functions of the monitor, under certain conditions. **Col 5, ll. 28-29 "Optionally the monitor may have onboard data processing and/or display."** If the Examiner considers that the PDA is a typical computer because it can provide the same functions instead of the monitor (in order to interpret the PDA is a typical computer), then inherently any/all additional components that Mault teaches would be considered as a functional accepted part of the PDA. The following are a small amount of additional required or inherited components that Mault teaches that are relied upon for the function of Mault's invention: See. **Mault #178 col.19.ll; 40-41 "The PDA..may provide the radiation for reflection oximetry of a skin part."** It would be inherited that the use of a microphone and recording capabilities, radiation for reflection oximetry, imaging capabilities or electrodes are not components of a typical computer, as taught by Mault. Please see col. 8.ll; 1-2 ...**"the PDA....includes recording capabilities..."** ...Also see col.16. ll; 30 **"the PDA and includes electrodes", AND col.13.ll; 58-59 ..."PDA that contacts the chest and records an EKG signal..."AND (referring to electrodes) col.19.ll;28-31 **"The PDA may be adapted so as to have an imaging capability. Reflection imaging of part of the skin at two or more wavelengths (e.g. red and blue) can also be used to determine blood oxygenation."****

To simplify the concept the Applicant will provide "one" more that is from the referenced **Mault copending provisional Ser.# 60/178,979 Title: PERSONAL ACTIVITY MONITOR page3.ll;1-2 "In one embodiment the accelerometer is built into a PDA which is adapted to be supported on the body such as on the belt."** The reason that Mault must include these components into Mault's PDA is because Mault's invention cannot be interpreted as being a typical computer. Mault's invention does not and cannot work with the traditional medical device housings due to the restrictions of physiological monitors which are solely used with living organisms. Traditional medical devices are not constructed with living organisms, rather other materials, such as, medical plastic and polymer. Mault's invention cannot provide data from the normal gauged (non-living sources), of traditional medical apparatuses, in order to obtain or retrieve data, as the gauges or made of other materials, such as, medical plastic and

polymer. Mault must include additional non-typical components within Mault's PDA itself, so as to adequately signify proper function, in correlation with Mault's physiological monitors which supply complicated not typical tasks. **col.19.11;28-31 "The PDA may be adapted so as to have an imaging capability. Reflection imaging of part of the skin at two or more wavelengths (e.g. red and blue) can also be used to determine blood oxygenation."**

Mault's function of the invention could not be accomplished without including the aforementioned non-typical computer components. Without these components Mault's PDA cannot perform the complex task of processing and utilizing the basic data received from the physiological monitors in order to provide the function of Mault's invention.

Please remember: it is commonly known a PDA cannot obtain "any" data AND physiological monitors cannot process "any" data. It is the Applicant's belief that the Examiner does not consider that a typical computer has electrodes, a recorder, a microphone, radiation components, an accelerometer or any of the above components (required or inherently acquired), as conceived by Mault's invention. Applicant's invention does not require any of the above additional components in order to provide the function of Applicant's present invention.

#### **b. THE EXAMINER CITES:**

*The plug-in type sensors is a separate entity with its own housing to form an integral unit with the PDA; or may be inserted into an accessory slot into the PDA such that it is within a common housing as the PDA (col. 4, 11-41-56).*

Applicant's response:

To the contrary, Mault also teaches **col.5.11 23-25 "Alternatively, the physiological monitor may be operational without being interconnected or in communication with the PDA"**. Also see: **col.4.11;30-32 "The PDA need not be a unitary device, but, instead the components could be distributed"** AND Col.5.11;1-3. **"When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules**

The three above quotes from Mault evidence that the monitor and PDA, under certain embodiments, are not interconnected or in communication with each other.

The fact that PDA and monitor modules do not have to be connected or in communication, evidences they do not share a single power source. Whereas, Applicant has only one shared power source. See **Applicant Page 17, ll. 24-26 “In Fig. 4, the Power Supply 4 connects to Microcontroller Unit 7, Audio Storage Unit 6, and Audio Amplifier Unit 8...The Power Supply 4 also connects to the Gauge 2 within the Medical Apparatus 10...”**

**Col.5, ll. 23-25 “Alternatively, the physiological monitor may be operational without being interconnected or in communication with the PDA”**. Given the lack of interconnection or communication in many of the embodiments and only temporary connection in others, one can only conclude that the Mault PDA and monitor module do not share a common housing, yet alone a permanent housing, as claimed by Applicant. If both the monitor and PDA are not connected, nor in communication in any way, during certain embodiments, there can be NO common housing OR integral OR need thereof as a permanent required condition. With this revelation of Mault’s teaching’s, Applicant requests that the Examiner reconsiders her current position that the components of the monitor and the PDA of Mault as being the same as Applicant. If the PDA and monitor are not commonly housed the patent of Mault is not the same as applicant’s invention.

**c. THE EXAMINER CITES:**

*Specifically, the PDA has “software programs to prompt and remind a user to make use of the various physiological monitor modules as part of an overall health management system “(col.6, 11.45-61, it is the Examiner’s position that scheduled reminder prompts are sufficient to reject a timer unit).*

**Applicant’s Response:**

The above teachings of Mault that the monitors can be used without being connected to the PDA disprove the Examiner’s timer unit position, as in certain scenarios the PDA and monitor modules are never connected or in communication. Also see: **Mault ‘178 col.4.11;30-32 “The PDA need not be a unitary device, but, instead the components could be distributed”**. This is sufficient evidence that the timer unit in the PDA as interpreted by the Examiner is irrelevant, since the PDA may not be near the user for the user to hear the timer go off.

Also note, the above underlined portion in the Examiner's office action language shows a requirement of Mault further evidences that Mault's invention is significantly different than the Applicant's invention. Applicant's invention does not prompt or remind the user to make use of any distributed parts. Also *see* **Mault col.5.11;1-3 "When the monitor module is not in use the PDA may be removed and used for alternative purposes, possibly with other modules."** This is evidence that the computing device (e.g. PDA that has the timer unit), is not providing the prompts or reminders, as in certain scenarios it is not interconnected or in communication to prompt the user to make use of the monitor/modules as taught by Mault. Thus, under this new discovery of the PDA and modules having no connection whatsoever, a timer unit in the Examiner's rejection is inconsequential. See also **Mault col.5.11 23-25 "Alternatively, the physiological monitor may be operational without being interconnected or in communication with the PDA"**

With this understanding, Mault's invention is distinctively different and "not the same" as the Applicant's. The Applicant's invention is a solely "one" commonly housed medical apparatus that does not depend on "any" outside attached accessories (i.e. software), to provide any reminder prompts as all prompts are preprogrammed within the medical apparatus itself, prior to receipt of the medical apparatus by the user.

Applicant has already shown that in many embodiments of Mault, the PDA is not connected or in communication with any physiological sensor. Therefore, if a clock or timer could be used by Mault to send a reminder to the Mault user, to make use of the physiological sensor, the clock or timer cannot be in the PDA, as alleged by the Examiner, as it would have to be with the physiological sensor. Thus, showing significant difference between Mault's PDA/monitor module and Applicant's enhanced medical apparatus.

Mault clearly and concisely describes only one method of producing software, which is produced by the user, from data obtained from the PDA. See **Mault '178 col.24.6-8 "...the PDA is removed from the docking cradle and the data is stored for use in various software**

**applications.**” This is the only concise evidence that Mault provides and requires for software to be produced. Under the governing patent statute. **35 U.S.C. § 112** “*the specification shall contain a written description...in such full, clear, concise and exact terms....*” It is believed that Mault complied with the above specification rule only with the PDA/docking cradle relationship to provide various software. Thus, with this understanding, Mault’s software prompts or reminders using voice recognition/generation/recording to supply appropriate voice is insignificant and inadequate to fulfill a true therapeutic or other medical requirements. This is why Mault solely relies on healthcare and fitness programs as his main focus per usage regarding software due to the simplified concise voice prompts provided under these conditions.

With this understanding of how Mault’s software is produced, the Applicant respectfully submits that the method that Mault teaches is not the same as Applicant’s invention. All voice prompts of Applicant’s invention are provided from preprogrammed binary/resource codes especially created with Binary Code Voice technology for each apparatus. The preprogrammed voice prompts emanate from within the medical apparatus itself. Applicant’s voice instructions require no production of software (as Mault teaches) to allow the voice to be utilized to provide voice prompts and no outside requirements of the user.

**d. THE EXAMINER CITES:**

*Additionally, during use of the monitor modules, the PDA utilizes voice recognition/generation capabilities to generate voice commands “to instruct the user on proper use of the monitor module and/or to provide feedback and results.” (col.5, 11.4-18). Although Mault only teaches a PDA speaker/headphone jack specific to the EKG/heart sound module (see col. 13,11-57-64, col.14, 11.43-50 and Fig. 11); however, it is inherent that PDA with voice generation is at least equipped with a speaker/headphone jack such that it is able to provide voice commands to the user.*

Applicant’s Response:

See Mault '178 Col 5., ll. 10-12 **"If voice recording or recognition is available in the combination, this capability may be used..."**. Voice generation capabilities makes Mault's also different from Applicant, as Mault use of voice is unreliable due to availability conditions. Applicant's voice capabilities are "always reliable" and "always available" within Applicant medical devices at all times.

**e. THE EXAMINER CITES**

*In regards to claims 4-8, 14-16, 19-21 and 25-27, voice commands are generated to instruct the user on proper use of the monitor module and/or to provide feedback and results (col.5,11.4-15). In the health/diet management embodiment, the PDA carries health management software to enable the user to set up a variety of fitness plans including personal goals and targets (this is interpreted as the level setting unit), to track the user's adherence to the plans, and to provide feedbacks and recommendations (col.6,11.62-col.12).*

Applicant's Response:

The only supplied software by Mault as taught under voice generation is inadequate as it requires the user to produce software in a precise way as described in Mault and is the only way for specifically providing any software for use in Mault's PDA/monitor module system. See Mault '178 col.24.6-8 **"...the PDA is removed from the docking cradle and the data is stored for use in various software applications."**

With a main focus of the Applicant's invention pertaining to voice usage, the Applicant requests that the Examiner "carefully" read what Mault is truly teaching concerning voice generation. Voice generation of Mault should not be confused with Applicant's preprogrammed synthesized/annotated voices, as there is significant difference between the Mault's voice generation and the Applicants preprogrammed Binary Code Voice technology, required for providing voice messages to the user. Please also note that Mault does not claim voice as a preferred technology for providing instructions, as Mault offers as many as seven (7) methods

for instigating user interaction. In fact, Mault states; "any suitable method is acceptable." See **Mault col.24.11;64-67 "However, the user may interact with the PDA, (1) using a stylus, (2) voice recognition, (3) a roller-jog selector, (4) track-ball, (5) an interactive pad, (6) a finger-motion sensor, or (7) any suitable method."** This numerous possibilities of providing user interaction (including voice recognition) makes it obvious that Mault does not prefer any one embodiment nor teach any one embodiment as preferred over the others. – No method is required in particular by Mault.

Mault does not teach or mention voice generation in any of the following healthcare embodiments of Mault's patent: (1) Pedometer Module; (2) EKG/Heart Sound Module; (3) Body Fat Measurement Module; (4) Body Temperature Module; (5) Blood Pressure Module; (6) Oxygenation Module; (7) Ultra Sound Sensors; (8) Heart Rate Monitor; (9) Food Scale Module; (10) Bar Code Scanner Module; and (11) Other Modules.

Mault's Calorimeter Module is the only embodiment out of Mault's many embodiments that Mault suggest voice generation, and the Calorimeter Module has nothing to do with any of the medical apparatuses listed in Applicant claims, thus, Mault does not teach the use of voice generation in his patent relating to any medical device. Applicant does not list any apparatus remotely related to a Calorimeter in its claims, making Applicant's invention noticeably different than Mault's non-medical invention.

With the understanding that none of the other module embodiments described by Mault specify use voice generation capability, the calorimeter is the only embodiment used for voice, it would not be relevant to Applicant's invention as a non-medical method. Applicant claims using voice capabilities in all of Applicant's medical apparatuses

Mault does not care or require voice recognition/generation/recording as the mandatory method for user interaction as Mault teaches any suitable method as being acceptable. **COL 24, 11 64-67 "However, the user may interact with the PDA... (1) using any suitable method."**. Applicant's invention utilizes simulated voice messages as Applicant is replacing the normal voice coming from the ancillary medical assistant. Therefore, Mault fails to require voice recognition/generation/recording for the user interaction for the various embodiment of his



invention, as he teaches allowing any suitable method as being acceptable, which means that voice could be excluded in its entirety if one chose to. If not excluded, voice recognition/generation/recording is still significantly different from Applicant's preprogrammed voice technology.

Referencing Mault's co-pending provisional patent, Mault's voice recognition requirements are relied on for this particular method and for further understanding on how to produce it. **Mault '178, Col 5, ll. 15-18 "Voice recognition modules are more completely described in co-pending provisional patent application Ser. No. 60/212,319, which is incorporated herein in its entirety."** Mault only teaches voice recognition/generation/recording technology for providing instructions to the user, for all of the components (e.g. PDA, Monitor Module or Attached Accessory) of Mault's invention, in order to provide instructions to the user in only one non-medical module embodiment. Mault '178 is silent concerning any other voice technology, or any other method to produce voice instructions for user interaction.

Applicant's voice messages provide a means of treatment for the patient depending on therapeutic verbal/voice guidance as needed, emanating from the medical apparatus itself. This Binary Code Voice technology is based upon hundreds of thousands of simulated/annotated voices within Applicant's Binary Code Voice technology system. These instructions are based upon the guidelines of governmental regulatory agencies (i.e. AMA, FDA, AARC and many others), set to provide safety and regulatory requirements for therapeutic use of medical devices. Mault teaches under one embodiment (Spirometer Module), that the user takes only several breaths as opposed to hundreds of breaths required under normal therapeutic repetitive exercise usage. Mault does not teach any therapeutic usage with any embodiment in Mault '178. **See Mault col.11.11;9-11 "According to one embodiment, the flow profile of a breath or the average of several breaths is presented graphically on the display of the PDA..."**The AARC (American Association for Respiratory Care) require under their guidelines, for the patient to take as many as one hundred breaths per day especially related to critical care situations (i.e. post surgical or hospital ICU setting). However, the AARC guidelines suggest using a Spirometry device up to 10 breaths per session, every hour per day, as many as 100 times a day.

As a general rule, with a PDA, even a small vocabulary can be hard to recognize especially if it contains confusable words, which is not uncommon in a critical care situation. As a general rule, for example, the 26 letters of the English alphabet (treated as 26 "words") are very difficult to discriminate because they contain so many confusable words (most notoriously, the E-set: "B, C, D, E, G, P, T, V, Z"); an 8% error rate is considered good for this vocabulary. Applicant's voice system is preprogrammed with simulated/annotated perfectly recognizable words, offering the user a perfect vocabulary in any language. This eliminates user input Mault teaches, in order to provide voice instructions. Mault only teaches voice generation in one non-medical embodiment and does not offer any variety of languages and requires user voice input. Mault's voice method is clearly different from Applicant.

In light of the differences between Mault's voice generation and Applicant's new preprogrammed Binary Code Voice ("BCV") technology, there is obviously a significant difference between the two. Mault requires the user to participate to acquire instructions. See **Mault co-pending provisional Ser. No. 60/212,319 Pg. 1.111-2 "A user who wishes to record information on PDA presses a record button and speaks into a microphone. Later, the recorded information may be played back."** AND Pg. 2.1118-19 **"Also, users do not consistently pronounce words so the software must be trained to recognize a specific user."** Applicant's voice instructions are preprogrammed within the medical apparatus itself and are synchronized to the exact requirements of the medical device being used and do not require the user to perform any input of voice participation, other than following the voice instructions, automatically provided by the apparatus itself. See **Applicant Page 7, ll. 1-5 "...it is not required to allow the patient to set any adjustment and the preferred method of function of the present invention may be to not allow the patient to have any control over the medical apparatus that is being used in relationship to the function of the present invention rather only allow the patient to follow the directions provided..."**

Applicant's voice prompts are capable of continuous prompts, phrases and commands and the voice commands of the Applicant's invention are capable of multi-tasking so as to give a verbal measurement while verbally directing the patient to perform the next session, in

correlation with the necessary level setting, all at the same time, without any human intervention. With the obvious difference in voice prompts and voice capabilities of the Applicant's invention, the Applicant respectfully submits that Mault's voice method is based on the input of the user, as taught by Mault (i.e. voice recognition, generation, recording), for each instruction needed and different than Applicant. The Applicant's submits that the two types of voice prompts are not the same and respectfully requests that any/all rejections be omitted.

Additionally, Applicant's invention continues to prompt the user to begin to use the medical apparatus until the patient "actually" uses the medical apparatus. See **Applicant Page 9, ll. 15-17** **"..will prompt the patient to start using the device by constantly prompting usage, until the patient begins to use the present invention again."**

**f. THE EXAMINER CITES:**

*In the body temperature monitoring embodiment, the PDA is able to determine a user's temperature in relation to a real-time clock, and provide warnings and treatment recommendation when the monitored temperature exceeds a pre-determined limit (col. 17, 11.2432, 11.45-55).*

Applicant's Response:

Mault's physiological monitor cannot work with a traditional gauge for measuring temperature as in traditional hospital gauged thermometer (i.e. non-living organism). The medical device relies on a mechanical pressure gauge. Applicant's invention solely works non-living traditional gauged medical apparatuses. Thus, this represents another example of why Mault does not teach any traditional medical usage for Mault's PDA/monitor module system where a physiological monitor module cannot be used. Furthermore, in co-pending referenced provisional application no. 60/117,011, Mault teaches that the clock need not be in the PDA at all times. See **Mault '011 provisional Mault, Pg. 1, ll. 12-13** **"This signal may be sent continuously or on regular intervals based upon a clock contained in the unit [i.e. transducer]."** This clock, which determines when the signal representing the body temperature is sent, is not in the PDA, which evidences the distribution of the components, as opposed to a

single permanent common housing. Mault provisional 60/177,011 also states at Page 1, ll. 7-8 **"..may transmit the temperature information to a remote location through a wired or wireless connection to the phone system, the internet, or the like."** As the transmission is not through the PDA, this further evidences no interconnection as well as Mault requires outside system to perform the function of the invention.

**g. THE EXAMINER CITES:**

*In the EKG/heart sound monitoring embodiment, the PDA is equipped with additional analog and digital filtering circuitry to process the patient's heart sounds (col.14, 11-43-67).*

Applicant's response:

Please note that in this embodiment, Mault solely teaches that the only sounds heard are the sounds of the patient's heart. No voice generation or voice instructions are taught by Mault, relating to the EKG/heart module and whether Mault uses analog and digital is insignificant in light of the Applicant's cited differences Mault and Applicant.

**h. THE EXAMINER CITES:**

*In regards to claims 9-13, 23-24 and 38-40, during health management, the patient is prompted periodically by the PDA to make use of the various physiological monitor modules as part of an overall health management (col.6, 11.40-61). For example, when a user has specified that he/she will walk or run a certain number of times for a certain distance each week, the PDA's software is able to prompt the user to remind them that, according to the schedule, they should use a pedometer module to monitor the specified activity (col.6, 11.62-12). The PDA stores the measured data when the user chooses to initiate the specified activity, or the PDA may allow the user to postpone the measurement until a more appropriate time (col.6, 11.45-61). Although Mault et al. does not distinctly disclosed that the PDA's prompts contain verbal messages, it does teach that the PDA and various monitor modules have voice generation capabilities for generating voice commands to instruct and provide audio feedback to the user (see col.5, 11.4-15, col.7, 11.59-col.8, 11.22). It is the Examiner's position that this is sufficient to reject verbal messages.*

Applicant's response:

The applicant invention automatically initiates the time and reminders as the user is not allowed to participate in initiation. Applicant's invention is preprogrammed for critical conditions and the medical device being used determines the required treatment for the patient. The patient does not decide when to initiate a therapeutic requirement, nor does the patient get involved in voice scheduling as to when the voice prompting messages should be sent. Additionally, Applicant's invention continues to send prompts until Applicant's invention determines that the patient has met the required therapeutic performance or as needed with each medical apparatus. Mault fails to teach any continual, repetitive, therapeutic voice prompts for patient usage.

Thus, all the aforementioned examples of promptings in Mault require the user to perform many functions on their own (in order for the PDA/monitor module system to be used). Thus, Mault's invention is not the same as Applicant. The Mault user is required to initiate when the pedometer will be used or when prompts will be sent. The main purpose of the Applicant's invention is to eliminate the need for any ancillary medical assistance so as to allow the patient (who is sick), to "not" have to perform any work, thus, allowing the medical apparatus itself to guide them effortlessly. The Applicant's invention requires no actions by the user to help the medical device concerning what time to do a therapeutic session or when to stop using the apparatus, as the Applicant's medical apparatus does these actions on its own. No setup work is done by the user. If the user must be required to help the invention work to perform a function it is different than the Applicant's invention. Applicant's invention has improved upon "traditional" medical apparatuses, in order to provide a more convenient way to allow the medical apparatus to perform any work necessary without medical assistance and without any participation (for set up) by the user. This is a main purpose of Applicant's invention and such is not achieved by Mault '178.

**i. THE EXAMINER CITES:**

*In regards to claims 28 and 30, relating to software the PDA communicates with remote communicating device such that patient's data can be further transmitted to the remote location for storage or analysis (col.7, 11.12-26).*

Applicant's response:

Please see Mault col.5.11 23-25 "**Alternatively, the physiological monitor may be operational without being interconnected or in communication with the PDA.**" It would be obvious that no patient data can be transmitted from a remote location under certain scenarios where the PDA does not have any communication with the physiological monitor as taught by Mault.

**I. RELEVANT CITATIONS**

Relevant citations in the 60/194,126 provisional include, more than just the PDA-monitor/module combination as Mault uses many other nontypical devices to provide the function of his application. See U.S. Provisional Application No. 60/194,126:

- b. Mault '126 Page 2.11;30 & Page 2.11;1-2 "Feedback messages to the user may be returned using the network either to the..(next page)..**interactive television** to the PDA or **any electronic device** capable of receiving and displaying the information." Applicant requires no outside medical parts (i.e. network or interactive television).
- c. Page 4. 11;11-13 "**The interactive TV** may also collect other information (e.g. related to lifestyle, health or diet) as a result of, or as a condition for, certain actions."

The following non-limiting examples of direct statements from Mault '178 support that Mault's physiological monitors and PDA are contained in separate housings and are not within a common housing as claimed by Applicant.

**A. MAULT '178 Patent**

1. Col 5, ll. 23-25. "Alternatively, the physiological monitor may be operational without being interconnected or in communication with a PDA."

2 Col.5.ll;1-3."When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules."

3 Col.4.ll;30-32 . "The PDA need not be a unitary device, but instead the components could be distributed."

4.Col.12.ll;33-34 "In this embodiment, the pedometer module 90, does not directly interconnect with a PDA."

5 Col.10.ll;24-26. "For example, if a cellular telephone is to serve as the PDA, the docking interface would take the form of a telephone docking station of some type."

#### **B. Additional MAULT Provisional Applications**

In addition to the Mault '178 specification and the above noted '126 provisional application, Mault '178 specifically incorporates and relies on numerous other Mault provisional applications to provide a complete disclosure for his invention. As shown below, these provisional applications also contain direct statements that support that Mault's physiological monitors and PDA are contained in separate housings and are not within a common housing as claimed by Applicant. Non-limiting and non-exhaustive examples of the direct statements include, but are not limited to, the following:

##### **1. U.S. Provisional Patent Application Serial No. 60/219,070**

a. Page 3.ll;24-25.."Feedback, generated by a specialist or computer expert system, may be transmitted to the PDA from the remote computer network."

b. Page 9.ll;29-30 "An insulin pump is preferably in communication with the PDA, e.g. using Bluetooth radio communication."

c. Page 8.ll;19-21 "If there is no response to the warning, the PDA may communicate with a remote device e.g. using a wireless internet connection to summons medical assistance."

**2. U.S. Provisional Patent Serial No. 60/195,779**

Page 1.11;3-7 "This invention relates to a unitary device adapted to be supported on the body of a user. The device incorporates one of a variety of forms of the physiological sensors such as position and/or attitude, temperature, calorimetric, ion sensing or the like..." Please note that the unitary device referred to in this provisional is only the sensor/monitor module and not a part of the PDA, which is obviously referencing a distributed device.

**3. U.S. Provisional Patent Application No. 60/117,011**

Pg. 1, ll. 10-11 "This signal may be sent continuously or on regular intervals based upon a clock contained in the unit [i.e. transducer]." The clock is described as being in the transducer unit and not the PDA, which evidences the distribution of parts of the components as taught by Mault, as opposed to a single permanent common housing as taught by Applicant. *The Examiner's interprets that the clock is contained within the PDA. However, in this particular embodiment, Mault teaches that the clock is within the transducer (which is obviously different from the Examiner's PDA-clock assembly interpretation). The Applicant's clock is always within the electronic assembly of Applicant's invention and is not separated or distributed as Mault teaches.* Col 4, ll 30-32 "The "The PDA need not be a unitary device, but instead the components could be distributed."

**4. U.S. Provisional Patent Application Serial No. 60/179,882**

a. Mault #882 Page 2.11;4-7 "The distance and rate information may be treated as other physiological measurements and transmitted to health care professionals over the Internet to allow tracking of the user's exact activity." Mault teaches in this quote that Mault's invention relies on medical assistance to provide the function. The function of the Applicant's invention is focused on reducing or replacing, medical assistance. Mault's obviously does not. Col 5, ll. 23-25. "Alternatively, the physiological monitor may be operational without being interconnected or in communication with a



**PDA.**” Nowhere in Mault ‘178 is it stated the monitor modules and the PDA share a common housing or are permanently connected and the above direct statement from Mault further supports that the monitor modules, under the above embodiment are not even in communication with the PDA. Furthermore, as described herein by Mault, the PDA itself does not have to be a unitary device. (Col 4, ll 30-32 **“The PDA need not be a unitary device, but instead the components could be distributed.**) This significant fact of operation of Mault PDA and Modules as shown in the above embodiment (are not interconnected) differentiating between Mault and Applicant.

Applicant claims and teaches that the Applicant’s present invention is unitary and in a common housing within the medical device itself. **Figures 3 and 4 and Page 17, ll. 16-18 “...the present invention and the Medical Apparatus Constructed By Constructor 10 are contained within the same Housing 14.”** Applicant’s claimed invention requires “no” temporary insertion or plug-in requirements or distributed parts at all. Applicant’s electronic assembly is “permanently” contained within the housing of the medical device and is incorporated in synthesis with the medical apparatus itself. **(Applicant Figure 3 and 4 and Page 2, ll. 28-30 “...by employing the use of audible, verbal, simulated human sounding voice or voices, produced with appropriate electronic technology in correlation and synthesis with said medical apparatus...”)** Applicant does not require any voice input by the user after, during, or before a procedure, in order to provide the function of Applicant’s invention. Applicant requires no temporary docking of any distributed parts nor requires any technical support via the Internet as Mault teaches. See U.S. Provisional Patent Application Serial No. 60/219,070, Page 8.ll;19-21. **“If there is no response to the warning, the PDA may communicate with a remote device e.g. using a wireless internet connection to summons medical assistance”** Applicant’s function of the present invention is to reduce or replace ancillary medical assistance. Whereas, Mault’s invention obviously requires medical assistance to function. See Mault co-pending provisional 60/219,070, Page 3.ll;25-26 **“...the PDA may send out a request for medical assistance”** and Page 8.ll;8-10 **“...the PDA may**

**communicate with a remote device e.g. using a wireless internet connection to summon medical assistance".**

Mault teaches that the PDA may be removed so that it may be used with a plurality of modules, Col.5.II;1-3 **"When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules."**. Mault's allowance of multiple uses and placement of "one" PDA obviously makes the PDA a problem to find. This is especially true if more than one PDA is being removed from different users, at the same time, or if any one PDA is misplaced due to human error, especially when a patient needs to use the misplaced PDA for continuing the life saving therapeutic usage required for recovery. Applicant's invention is never removed from the patient, under therapeutic treatment conditions and is not allowed to be used by any other person other than the person performing therapeutic treatment with the medical device. The referenced incorporated provisional applications in Mault show that the monitor modules are not in a common housing with the PDA, as the embodiment Mault teaches are not permanently docked or interconnected or in communication with the PDA at all times as stipulated in the aforementioned scenarios that Mault teaches. Mault teaches that the PDA is removed from one person to another person, so that the PDA can be used for other purposes. See aforementioned quote. This would "not" be possible under therapeutic time constraints or treatments, using traditional medical devices, as under patient therapeutic usage the medical apparatus must be ready for use at all times. Multiple persons using the same PDA would make it a requirement for medical assistance to constantly be present and prepared to supply the PDA to different patient's as needed. Applicant's teaches that all of the parts of the electronic assembly are permanently disposed within the housing of the medical apparatus and the medical apparatus remains with the patient/user throughout the complete treatment without being removed from the user. Fortunately, the Applicant's medical device is not used by multiple users, for obvious reasons, (in particular transmitted diseases).

Applicant respectfully requests that the Examiner consider the true function of both Mault and the Applicant, as it is imperative to emphasize the structural differences between the two, as neither are the same in anyway. Applicant's invention uses the housing of the medical

apparatus, which is the traditional existing structure of the common housing of the medical apparatus itself. Whereas, Mault's invention solely pertains to physiological monitoring in order to obtain data from living organisms (i.e. human beings), not data directly from a medical device made out of non-living materials (i.e. polymer, etc.), which Mault's monitor modules cannot detect due to their specialize required abilities. Mault's structurally requires use of either the PDA or the monitor module and never comes into contact with any traditional device as Applicant.

The Examiner interprets Mault's invention as being integral. However, please note the definition of "integral" does not equate to common or the same housing. Relevant definitions for the term "Integral" show that the word means (1) essential to completeness; (2) formed as a unit with another part or (3) composed of constituent parts. Clearly, Mault's components/parts are not located in a common housing.

Mault solely teaches the invention is only used within the parameters of the PDA and physiological monitors, as all of his embodiments are considered within these boundaries meaning; time spent setting up voice or equipment by user before usage. Mault does not and cannot improve any standard or traditional medical apparatus, as Mault is limited to the confinement of the two basic components (e.g. Physiological Monitor Modules and PDA), each with their own separate housing.

In summary, Applicant's claims that the Applicant's electronic assembly is contained within the housing of the medical apparatus, such that, the electronic assembly is permanently in synthesis with the medical apparatus without any special conditions, sharing a common housing at all times. Mault clearly fails to teach this feature of Applicant's claimed common housing device, as Mault teaches that the parts may be distributed. **Col 4, ll. 30-32 "The PDA need not be a unitary device, but instead the components could be distributed"**. This is a fundamental difference between Applicant's claimed invention and the Mault device and sufficient by itself to permit Applicant's claims to be allowed over the Mault patent.

**II. Mault's References To Voice Generation And Voice Recognition Is Not The Same Or Equivalent To Applicant's Humanlike Verbal Prompting Messages And Instructions.**

Applicant teaches the utilization of a unique micro-electronic system using Binary Code Voice (BCV) technology, Applicant's medical apparatus automatically verbally prompts the user when it is time to use the medical apparatus as well as, provides voice guidance on the use of the medical therapeutic procedures as needed and provides voice instructional messages to the patient and the appropriate voice encouragement based on the patient's performance. BCV technology permanently pairs with existing conventional medical apparatus "in synthesis" with each device, without changing the structural design of the traditional equipment itself. This combination of technology and structure is unnoticeable to the user. Applicant teaches a different and new way of providing voice prompts, voice guidance or voice instructions, for use of each medical device, in relationship to the patient's treatment without any user input. Applicant has improved upon medical apparatuses by incorporating a new technology of voice guidance and voice therapy, as pertains to traditional medical devices. Mault has not improved on the existing PDA regarding any voice usage, as Mault teaches that PDA's may have voice capabilities only in some PDAs and only if available, as Mault indicates that "if" the PDA already has voice generation capabilities, voice instructions may be provided. Mault teaches that "any" means for providing user interaction is acceptable as Mault does not truly rely on voice generation at all, unless the PDA has voice capabilities as some PDA's do not. Remember, voice generation is only "one" method of the many methods that Mault suggests for user interaction. **See Mault '178 Col 24, ll 64-67 "However the user may interact with the PDA using a (1) stylus, (2) voice recognition, (3) a roller-jog selector, (4) a track-ball, and (5) interactive pad, (6) a finger/motion sensor or (7) any suitable method."** In fact, Mault does not improve on any voice methods (i.e. recognition/generation/recording). Mault merely makes reference to usage "if" voice generation is available as it is limited to only some PDA's that can provide voice generation. Only then can voice generation be used to instruct the user, as Mault teaches. Otherwise, the PDA is not able to be used in any scenario in which the PDA does not have voice

generation capabilities (albeit the voice messages of Mault and Applicant are distinctly different).

Mault solely teaches an existing commonly known voice technology, called voice recognition/generation/recording, (this means that the PDA must first recognize the user's voice, which the user records into the PDA to generate voice instructions). Mault's voice generation can only be achieved by the user talking into the recording processor of the PDA and then the user can replay the instructions at a later time, providing some words and reminders through the PDA. To use Mault's voice recognition/generation, one must first speak words into the PDA which are recognized through recording them, in order to obtain "voice generation" for later instructional usage. Mault specifically requires the reader, when reading Mault's patent, to reference Mault's particular intentions of the correct teachings of both voice generation and recognition during user input. Under Mault's teaching, Mault requires the reader to read further co-pending provisional references in order to fully understand Mault's voice recognition in its entirety. (See col.5.11;14-18 **"Voice recognition modules are more completely described in co-pending provisional patent application Ser. No. 60/212,319, which is incorporated herein in it's entirety."**) Mault also recognizes that this combination is required in order to have voice capabilities. See col.5.11; 10-12 **"if both voice recording or recognition is available in this combination, this capability may be used to control the module and/or annotate results."** As an example of how voice recognition is regenerated for the PDA, Mault teaches in referenced co-pending '#319 the following: **PG.1, ll. 1-2 "A user who wishes to record information on PDA presses a record button and speaks into microphone. Later, the recorded information may be played back."** Mault also suggests that the user may speak numbers in a microphone of the PDA for later instructional usage (through the user speaking at least 10 different choices into the PDA to adequately supply a coordinating instruction for each selection of the PDA, such as 0 through 9) but this is still too complicated under a hospital/patient scenario, especially post surgical, as many times the patient's voice is slurred due to surgery or medication.

Though Mault goes on to teach the preferred embodiment of the PDA having the ability to simply understand these numbers for voice generation, Mault always requires set-up work by

the user to adequately supply voice recognition/generation/recording. See **Mault Provisional No. 60/212,319, Page 2, ll 11** “Also users do not consistently pronounce words, so software must be **“trained to recognize a specific user”** and **Page 5, ll. 5-6** “If the user wishes to choose hot cereal, they pronounce the word two.” Before Mault’s voice generation information can be provided by the user, Mault requires the user to talk into the recording processor of the PDA with the instructions and only then can the instructions may be played back at a later time. This makes true use of Mault’s voice generation instructions invalid as they are too complicated for a real life medical situation (i.e post surgical). Traditionally, these verbal messages would be required by an ancillary medical assistance, who would be directly working with the patient to confirm that the patient usage of the required procedure of the medical apparatus is being followed precisely (i.e. repetitively performing the therapeutic sessions required), thus, expediting recovery time and compliance by the patient. Applicant’s electronic assembly, (power source and speaker, etc.) are all disposed within the housing of the medical apparatus at all times (i.e. voice messages and prompts, before, during and after use of the medical apparatus), as no outside help is required to instruct the patient’s performance of the function of the invention. **Applicant Page 11, ll. 1-3** “...by continually reminding the patient until the performed requirements required by that apparatus being used are met.”

Under a critical medical situation (i.e. hospital, ICU) a patient/user would obviously be confused by the proper voice techniques required by Mault’s voice recognition/generation. Perhaps this is why Mault teaches home usage and overall healthcare/fitness programs, rather than complex medical usage (i.e. hospital, repetitive therapeutic requirements, or critical medical situations, etc.). **Applicant Page 8, ll. 24-25** “...will prompt the patient to start using the device by constantly prompting usage, until the patient begins to use the present invention...” Applicant’s claimed invention eliminates the need for outside ancillary medical assistance or any participation by the user regarding set up, or helping create the function of the medical device (i.e. no calibration or voice input required). With Applicant’s invention, the user receives automatic voice prompts and voice guidance according to each required therapeutic session that a patient is performing, as well as a verbal reprimand, when the user does not reach the correct goal and provides praise when the patient exceeds their previous performance. See

**Applicant Page 7, line 27 – Page 8, line 1 “When one reaches his or her particular goals, or completed the function of that apparatus utilizing the present invention, an audible verbal response in the unit will give an immediate indication of whether their perspective goals have been reached, through audible, verbal, simulated humanlike voices, giving the exact measurements and helpful incentive to encourage the patient to try harder or verbally confirm that the patient has achieved their goal accordingly.”**

The medical apparatus on its own utilizing BCV technology, through hundreds of thousands of prerecorded synthesized voice prompts provided to the user, prior to the user ever receiving the medical apparatus, by using technology that contains logic and mathematical calculations to assure proper voice instructions are given to the user. See **Applicant Page 10, ll. 26-28 “...by giving incentive to the patient, or gauging the patient’s performance through the function of the present invention as specified herein, capable of performing mathematical and logical calculations and decisions logics...”** See also **Applicant Page 6, ll. 13-15 “This availability to audibly and verbally hear the accurate readings and encouraging phrases to prompt usage by the patient will help the patient reach whatever goals or therapeutic pronunciation of exactness towards those goals...”**

Mault does not teach an electronic assembly that includes voice prompts and phrases and preprogrammed or customized voice messages or multitasking (i.e. several separate voice functioning), for Mault’s PDA/monitor module. Applicant messages are stored within the medical device, prior to the user ever receiving the medical apparatus. No set up work is required by Applicant’s user in order to receive any voice prompting, voice guidance, voice instructions, or voice measurements. Applicant’s user simply follows the automatically generated voice messages from the medical device for therapeutic guidance and medical usage, as needed. **Applicant pg.6.ll.26-28 “...the main purpose for the audible, verbal human voice commands or responses as provided by the present invention is to prompt usage of the above said apparatuses in order to improve whatever condition is being treated.”** Mault teaches simple non-constant, non-repetitive voice prompts. Applicant prompts constantly providing voice guidance to ensure that the patient is compliant. The more the patient usages the medical therapeutic equipment or medical apparatus the faster the patient recuperates. Mault’s invention

does not repetitively or constantly inform or prompt the user when to use the module, as would be required for a therapeutic treatment. **Applicant Page 11, ll. 1-3 "...by continually reminding the patient until the performed requirements required by that apparatus being used are met."** To the contrary, the Mault user tells the PDA when the user wants to receive the voice instruction or information. Thus, not only does Applicant's invention give repetitive instructions to ensure recovery, Applicant also supplies voice measurements. Applicant's claimed invention provides constant verbal voice prompts to ensure compliance by the patient, a claimed feature of Applicant's invention that Mault is completely silent about. Some non-limiting examples of the benefits provided by Applicant's improved medical apparatus, include, but are not limited to, providing long phrases and verbal measurements, simultaneously having the ability to turn "off" and "on" each day, for weeks at a time, to provide a voice response to awake the patient and a voice response to when the patient treatment can be discontinued. Mault's voice capabilities of the PDA/monitor combination are not adequate to perform complex repetitive, lengthy, therapeutic exercise or patient usage promptings or guiding the true capacity of elongated therapeutic treatment requirements for the patient. As the Examiner pointed out, Mault only teaches short simple instructions (i.e. let's take a walk, OR time to take an aspirin). Please note that these voice instructions, through the process of voice generation, require that the voice and words must be supplied by the user's participation and input.

**"The PDA may display instructions to the user on how to use this spirometer module. The user then follows the instructions to use the spirometer module to measure the appropriate lung function, such as flow rate or lung volume"** and Col. 5, lines 4-5: **"During use of the monitor module, the PDA may display instructions for use."** See also U.S. Provisional Application Serial No. 60/179,682: **"The unit incorporates a display such as a LCD and user buttons or switches which allow the display of the desired information."** Applicant's sole and only method is Applicant's unique Binary Code Voice (BCV) technology, as the means for user interaction with each individual medical device. No other method is needed with Applicant's invention to supply user interaction.



Applicant's invention provides voice messages within each medical apparatus, which prior to the Applicant's invention was not available in the medical apparatus itself.

Thus Applicant does not require any spoken word by the user, nor is the Applicant's invention confined to any particular vocabulary in order to function. Applicant teaches a new way of providing complex verbal voice messages through BCV technology that is not associated with the already "existing and known" voice recognition/generation capabilities of some PDAs. By using the preprogrammed BCV technology of the Applicant, using voice synthesis and annotations Applicant provides a different more efficient voice messaging technology than Mault. Voice generation capabilities for a PDA of Mault's patent were not new or novel when Mault originally filed the application. Mault only suggests use of voice through user interaction, based on the fact that "if" the PDA regarding voice recognition, (*speaking and recording words*) and voice generation are available. Only then can Mault's voice instructions be used. Some PDAs do not have voice capability, which makes Mault's voice instructions unreliable, as it is not known when or if the function can be used. Applicant requires no voice input or recording of voice by the user, nor does Applicant's system require any training by the user. Applicant's BCV technology is not subject to any voice availability to provide function. All of Applicant's voice prompting and instructions of the present invention are pre-programmed within and in synthesis with the medical apparatus itself using BCV technology created by the Applicant which allow voice synthesis or annotations to produce perfect voice reproduction. There is no need to depend upon a separate existing voice recognition etc. method, as required by Mault to provide any voice capabilities for the Applicant's invention. Thus, Mault teaches, in connection with voice recognition/generation/recording that additional preparation and input by the user is required in order to instigate preparation of any voice instructions. Mault's user voice input for instructions makes it difficult, or impossible, in many cases (i.e. critical medical scenarios) for the patient to perform. Quite differently, Applicant's invention is easy to use as it is preprogrammed with all the voice commands etc. necessary in order to automatically prompt and instruct the user, without any voice input requirements from the user.

The beauty of Applicant's new Binary Code Voice technology is that it is not a pre-existing technology. However Mault's is. Rather, the Applicant provides a new and novel way to enhance each medical device with the necessary therapeutic voice instructions and verbal guidance, as needed, in accordance with the requirements of each medical device. Applicant's invention automatically provides the necessary therapeutic and voice instructions in order to expedite recuperation by the patient according to the treatment or medical procedure. Applicant's new system is intended to help reduce and replace ancillary medical assistance and verbally guide the patient to assure adequate recovery, per the guidelines of the medical apparatus being used and without outside assistance. Applicant's invention will guide and lead the patient through each of the required performance and guidelines of the medical apparatus in accordance with the necessary therapeutic exercises or medical procedures, as needed. This new technology ensures compliance by the patient in all medical scenarios (i.e. critical or otherwise).

**A. MAULT '178**

1. Col. 6, ll 27-30 "**Each of the above described embodiments and alternatives, as well as others that will be described, apply to each of the physiological monitors described herein below.**" *This means through Mault's own teachings; that all co-pending provisional applications referenced by Mault apply to Mault's '178 patent and may be used, as needed to argue and elaborate on a specific points of preciseness of Mault's teachngs.*

When the '319 Provisional is reviewed as directed by Mault, it is seen that Mault requires the user to record his or her voice as part of the set up for Mault's voice recognition/voice generation requiring additional work by the user providing voice input for the function of voice technology. See below:

**B. MAULT Provisionals**

**1. U.S. Provisional Patent Serial No. 60/212,319**

a. Pg. 3.11;4-6 "In a preferred embodiment, the PDA is capable of recognizing numbers 0 through 9 when they are spoken by a user."

b. Pg.4.11;7-8 "The hardware module includes a microphone for receiving speech and may include other controls such as an on-off switch and sensitivity adjustments."

c. Pg. 3, ll. 2-3 "In this situation, the speech recognition software must only recognize and distinguish between ten choices, all of which are reasonably distinct." Mault further demonstrates the user preparing the PDA for setting up playback instructions to provide feedback, Pg 5; 18-19 "For this purpose, the hardware module may also recognize the commands "up and down.""; Pg 5, ll. 5-6 "If the user wishes to choose hot cereal, they pronounce the word "two""; and Pg 2.11;18-19 "Also, users do not consistently pronounce words so software must be "trained" to recognize a specific user."

This further verifies that Mault's voice generation is not perfectly distinct in many instances.

d. Pg. 5, ll. 18-19 "For this purpose, the hardware module may also recognize the commands "up" and "down."

e. Pg. 5, ll. 5-6 "If the user wishes to choose hot cereal, they pronounce the word "two" .

f. Pg 2, ll;15 "The software must be capable of very accurately capturing the spoken word."

In many embodiments, visual display is one of the variety of interactive methods. It is also noted that only "one" module embodiment, voice generation is actually reference in Mault's specification (despite the exhaustive amount of pages that's Mault specification consumes). Though Mault discusses over thirteen (13), various module embodiments in Mault '178, Mault only refers to voice generation in "one" out of all of Mault's PDA/monitor module embodiments. Mault does not require voice to being mandatory for any function of his invention as Mault teaches that he does not require or care what method is used for the user interaction, as long as the user interacts. Mault does not require voice in any part of Mault's patent. Col 5, ll. 23-25. "Alternatively, the physiological monitor may be operational without being interconnected

**or in communication with a PDA.**". See also Mault '178 Col 24, ll 64-67 "However the user may interact with the PDA using ... any suitable method."

Mault teaches that text messages are sent from a remote location and in other embodiments from health professionals. See Mault '178, Col 18, ll. 18-22 "The health care professional could transmit treatment recommendations back to the patient associated PDA via the Internet or other public networks." Mault's voice generation is limited and requires user assistance and are not new or novel, nor does Mault state otherwise. Mault's voice generation does not conflict with or disclose the voice technologies of the Applicant's. Mault's teaching truly pertains to another area of usage (i.e. healthcare and fitness programs). Mault does not specify that any method is the method of choice as Mault obviously teaches that the main focus for user interaction only depends upon supplying a suitable method to appropriate Mault's PDA/Physiological Monitor Module system.

### **III Applicant's Claimed Invention Is Preprogrammed In Advance Of Receipt By The Intended User And Not At The Time Of Use As Mault's Device.**

Applicant's invention is preprogrammed within the housing of the medical device with the unique capability through complex advanced microchip technology (i.e. BCV technology which will respond with the adequate voice message when needed, to adequately reduce or replace ancillary medical assistance, by supplying the necessary voice message previously provided by ancillary medical assistance, By working permanently in synthesis with each medical apparatus the applicant's invention functions as a permanent component within the housing of each medical apparatus in order to supply a novel new addition to the medical industry and to promote patient compliance. Applicant does not require spoken words by the user (i.e. input or recording of the user's voice), nor is Applicant's invention constrained to having to be trained to recognize a specific user as discussed in Mault's 319 Provision. See Pg 2.11;18-19 "Also, users do not consistently pronounce words so software must be "trained" to recognize a specific user." Applicant provides a novel new way of providing complex

verbal voice messages not previously provided with the traditional medical apparatus and also different from existing voice message of a PDA as taught by Mault. All voice prompting and instructions of Applicant's invention are pre-programmed within and permanently in synthesis with the medical apparatus itself making usage effortless for the patient.

1. See Applicant Pg.8, ll 11-145 Applicant states *that the patient/user is "able to hear their settings, produced outputs, volumes, or ratios or any similar readings necessary to achieve the functions required, as well as any numeral context, but not limited to, relating to their input or preprogrammed function of the present invention."*

2. Pg 8, ll 14-167 also states that the "target measurement gauged by the present invention as programmed in synthesis with whatever apparatus is being used in which a gauge or similar device is used to show measurement."

Applicant's electronic assembly is contained within the medical apparatuses' housing and is permanently in synthesis with the apparatus at all times. Applicant's programming (i.e. functional program) deciphers patient information using logic and mathematical calculations and also contains the BCV technology which controls the components of Applicant's voice messages and the electronic assembly. Applicant's programming is preprogrammed and permanently contained within the medical apparatus itself. To the contrary, Mault discusses that the same PDA is used with multiple removable/insertable modules, in certain embodiments, whereas in other alternative embodiments he does not. Mault '178 Col.5.11;1-3 "When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules." and Col 5, ll. 23-25. "Alternatively, the physiological monitor may be operational without being interconnected or in communication with a PDA." Applicant's function of the present invention remains constant in each medical device being used. Mault does not. Applicant's unique electronic assembly is preprogrammed specifically for each medical apparatus and is in synthesis with the medical device which remains exclusively programmed to each specific medical apparatus' function at all times. This is a distinct fundamental difference between Applicant's invention and Mault's invention.

**IV Applicant's Claimed Invention Is Ready For Use By The Patient  
Whereas Mault's Invention Requires Set Up By The User Before It Can Be  
Used.**

Though the Examiner has not given any weight to the therapeutic use of treating the patient according to the therapeutic requirements set by the governmental guidelines for safety and regulation (i.e. a hospital requirements of traditional medical apparatus), Applicant respectfully submits that the Examiner's interpretation misses the importance of the physical condition of the user and the way the medical device is required to be used. Especially in a hospital. Mault obviously does not teach any use of the PDA/monitor module regarding any required guidelines for usage of Mault's system. As Applicant's invention is capable of working under the conditions of a hospital type setting, within these parameters which relates guidelines for medical devices, it is obvious that Applicant's is more complex in order to fulfill these parameters. Often the user has recently had surgery and/or another critical procedure and/or is suffering from a specific illness or taken medication which postulates the need to follow the exact procedure therapeutically required for devices being used in the hospital. Requiring the user as Mault teaches to set up or calibrate any medical device, is obviously not productive or conducive for post surgical medical recovery. For Applicant's novel invention, there is no requirement needed for "any" set up by the user and Applicant's invention is programmed for the medical guidelines per each medical device. Applicant's user never needs to be involved in any set up or calibration of the medical device. Whereas Mault's invention requires the user to do all of the assembly or pertinent input (i.e. record his or her voice, calibrate, connect one or more components to another component, program, instructions, perform set up or calibration of Mault's device).

Applicant also notes the following non-exhaustive examples in Mault where the user has to set up the device before it can be used:

A. MAULT '178

1. Col.7.line 10 "**The user may then insert the appropriate module into the PDA" and then "perform the appropriate test".**

2. Col. 7, ll. 59-60 "**In order to use the calorimeter module the user first docks the PDA into the docking interface.**"

3. Col 8, ll. 7-8 "**At a later time, the user may dock the PDA with another computer for downloading the information to the computer...**"

5. Col.12, ll. 49-52 "**In this case, it is necessary for the user to first transfer the memory module to the PDA in order to determine their exercise parameter.**"

## **B. MAULT PROVISIONALS**

### **1. U.S. Provisional Patent Application Serial No. 60/177,016**

Mault further states in this provisional that the PDA requires assistance and the user must enter information themself through said assistance. (*Pg.2.ll;12-14 "The PDA or PC preferably includes a program to assist the user in entering information relating to her food and beverage consumption...."*). The applicant requires no assistance and the patient is not required to enter any information in order to perform the functions of the medical apparatus. Applicant's claimed medical apparatus is ready for use immediately upon receipt by the user, as all functions of voice messaging have been preprogrammed within the medical apparatus prior to the patient receiving the medical device itself.

In Mault's Spirometer Module, Mault again depends on the user to do all of the work of setting up the Mault device, prior to such device being able to be used. See Col. 10, ll. 53-55: "**In order to use the device, the user first inserts the attachment flange into the accessory slot to couple the spirometer module with the PDA**" This above statement of Mault also provides supports for Applicant's other arguments as to Mault's PDA/monitor module system not being in a common housing. Please note that after the artificial breathing device is removed from the patient's throat (i.e. post surgical), the patient is in no condition to provide any voice input AND incapable of calibrate or any assembly of an accessory, in order to use Mault's device.

Given the assembly, calibration and set up of components required to use Mault's PDA/monitor module system, it is readily apparent that serious problems can occur with Mault's invention, especially in critical medical scenario. Under Mault's voice input requirements, Mault's invention is impractical in a real life critical patient situation, as components of Mault's invention (i.e. PDA) could be inadvertently removed longer than expected, through human error. The PDA could easily become unable to be reconnected, such as, if one of the components is misplaced. Under the Mault's teachings, when the PDA is removed, it is obvious that an ancillary medical assistant would need to be present to remove the PDA from the patient. In a situation where the PDA is misplaced, Mault's system could be incapable of performing "any" function required. Applicant's invention can also perform, as needed, without restrictions or situations that could cause separateness between the necessary components that are needed to fulfill the function of the Applicant's medical device. In fact, Applicant's invention improves upon Mault.

Applicant claimed device is ready for use upon receipt by the user. No work is required by the user/patient (i.e. calibration, user voice input, removing PDA, etc.).

With the extent of the information and examples provided above, in conjunction with the above amendments to the claims, Applicant respectfully feels confident that its case for novelty of its invention has been shown.

In view of the above Applicant respectfully submits that the many differences between Mault's invention and Application warrant reconsideration of the Examiner's rejection based on Mault. Accordingly, after reading the following remarks concerning the Mault rejection, in conjunction with the claim amendments, Applicant respectfully requests that the Section 102 rejection based on Mault be withdrawn and that Applicant's application be passed to allowance.

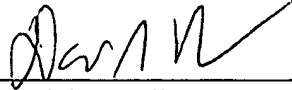
In view of the above, Applicant respectfully submits that the claims are all in condition for allowance. Applicant respectfully requests that the Examiner withdraw the objections and rejections. Accordingly, favorable action, allowing all of Applicant's claims, is respectfully requested. Applicant has completely responded to the September 14, 2010 Office Action.



In re application of: Terry Keith Bryant  
Serial No.: 10/767,396  
Page 54

If there are any additional charges, including extension of time, please bill our Deposit  
Account No. 503180.

Respectfully submitted,



---

Daniel S. Polley, Reg. No. 34,902

DANIEL S. POLLEY, P.A.

**CUSTOMER NO. 44538**

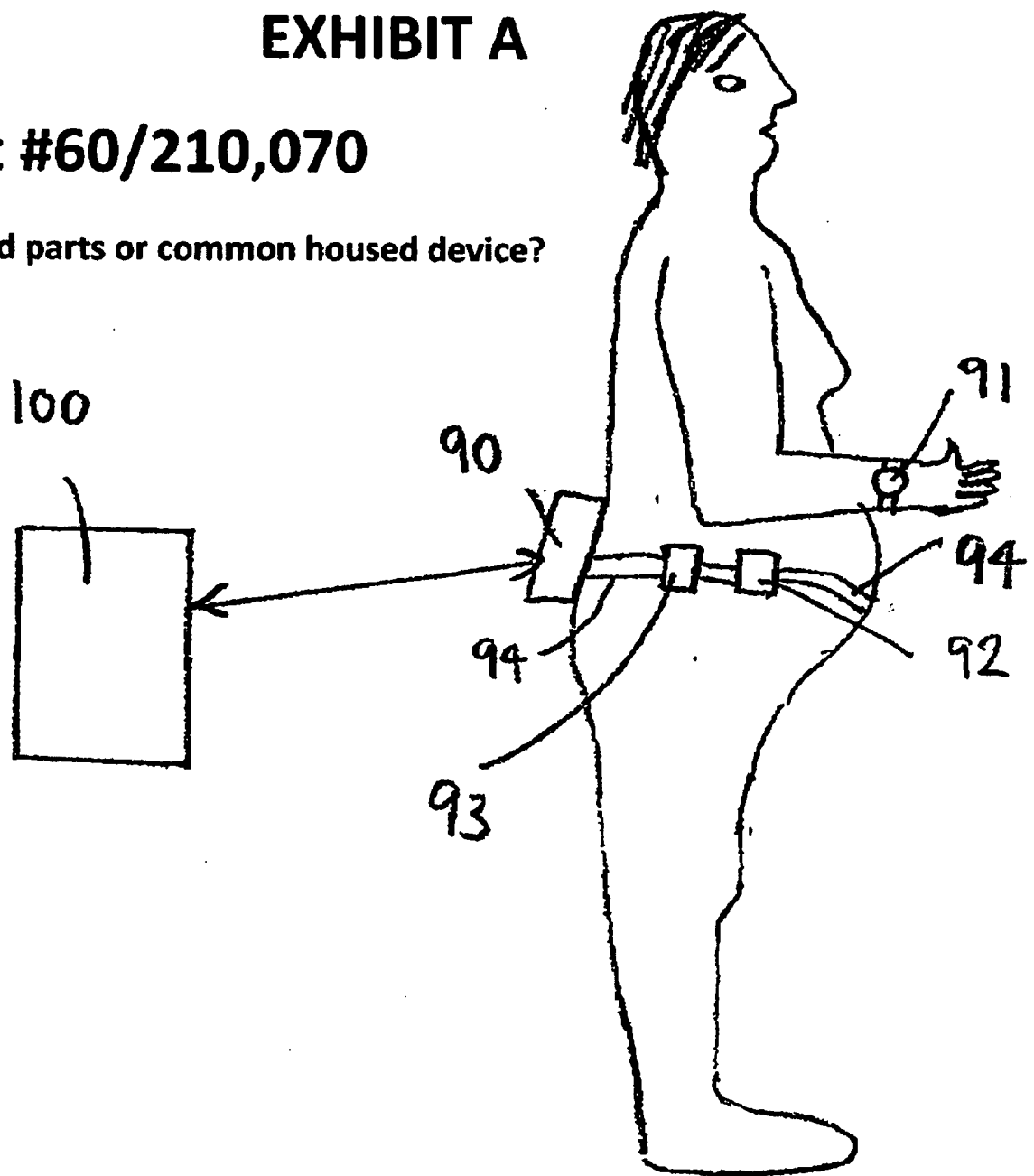
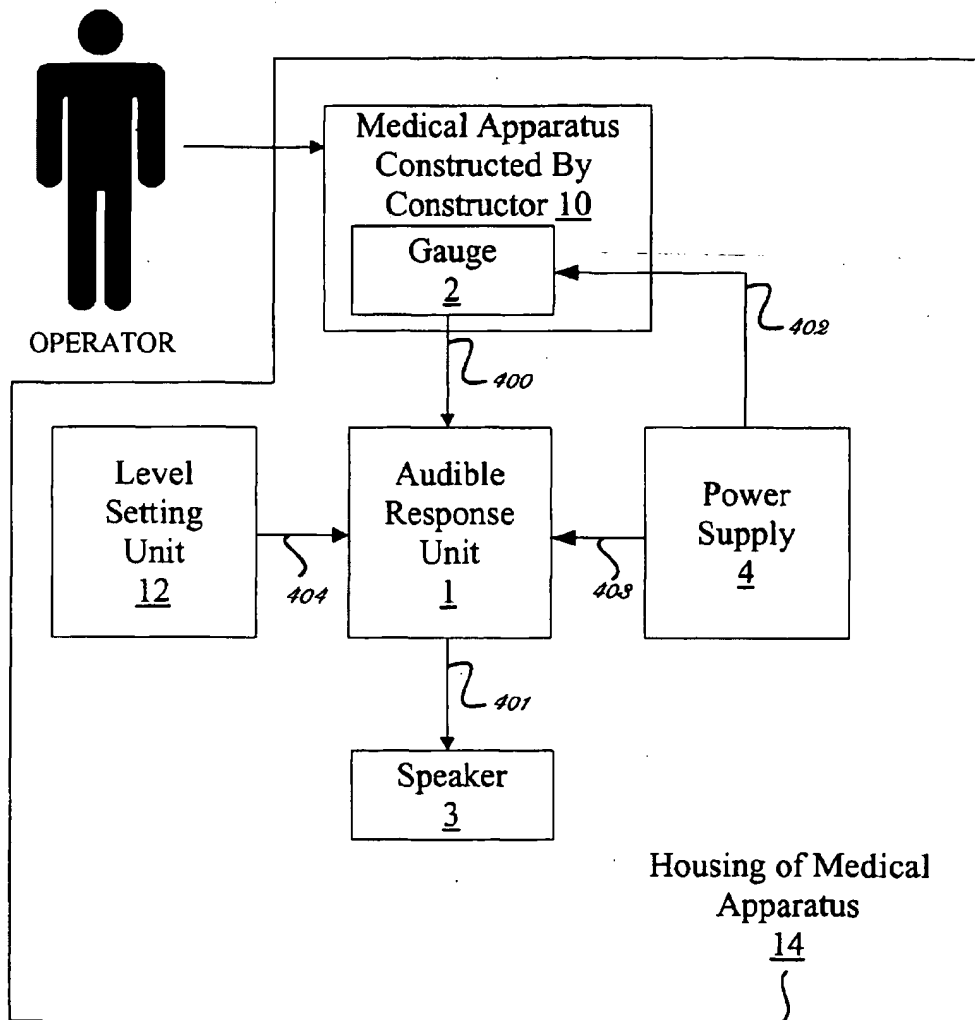
**EXHIBIT A****Mault #60/210,070****Distributed parts or common housed device?**

Figure 6

**EXHIBIT B**

Inventor: Terry K. Bryant

*Fig. 1*

Present Invention Within Housing of Medical Apparatus

## **EXHIBIT C**

### **APPLICANT'S PERSONAL MEDICAL HISTORY PROVIDING THE BASIS FOR APPLICANT'S INVENTION**

Applicant's own medical experiences serve as the inspiration for Applicant's invention. In 2001, Applicant had quadruple bypass surgery, which required the collapsing of Applicant's lungs as part of the procedure. In order to rebuild his lungs post surgery, Applicant was provided an Incentive Spirometer to rebuild his lungs to prevent pneumonia which is required certain established therapeutic guidelines for the use of the Incentive Spirometer. For each new therapeutic session, a nurse (ancillary medical assistant) would enter Applicant's hospital room and remind Applicant that it was time for the next therapeutic session and to begin using the Incentive Spirometer again. The nurse also remained in the room and provided instructions during each session, as well as, reviewed the Applicant's measurements achieved, providing encouragement based on the results. This pattern of assistance was repeated for each therapeutic session which was typically about 100 sessions per day for at least a week.

Seeing the amount of time devoted by the nurse to attend to Applicant's therapeutic sessions, provoked the idea for the Applicant to begin finding a way of reducing or replacing the tasks which were being performed by the nurse, possibly through automation. Over the next several months Applicant expanded on the types of functions that could be provided automatically and ultimately developed a novel electronic assembly to be used within the Spirometer supply simulated voice prompts regarding usage. Please note Applicant also suffers with several other health problems including: Type I diabetes, high blood pressure, heart attack, retina problems exasperated by the diabetes, neuropathy, which causes pain in the feet and limbs due to poor circulation, as well as, angina and V-fibrillation. Given Applicant's personal familiarity with these areas of medical conditions, Applicant naturally recognized the advantages of applying his invention to improve other medical apparatuses in addition to the Incentive Spirometer.

Applicant originally filed Document Disclosure for the inventions under the Patent Office's then Document Disclosure program. After the disclosure document filings, Applicant proceeded with non-provisional application filings for his novel invention incorporated within an Incentive Spirometer as well as filing the Applicant's all medical apparatuses application. Applicant's instant "All Medical Apparatus" application was filed on January 23 2004, which was then followed by the filing of Applicant's "Improved Incentive Spirometry Devices" application on March 26, 2004. Both applications were filed well in advance of the September 14, 2004 issue date for the previously unpublished Mault '178 patent relied on by the Examiner.

Applicant has already received two patents (U.S. Patent No. 6,942,625 and 7,591,789), both incorporating his invention within the housing of Spirometry Devices, in order to improve the Spirometer. It is the Applicant's belief that through the use of verbal voice messages for

prompting, guiding and instructional improvements, the patient in connection with the therapeutic Spirometer, should improve patient compliance, thus, quicker recuperation. With Applicant's new enhancement of the medical devices, Applicant's expects his novel voice messages will help with reducing or replacing ancillary medical assistance. The same basic concepts of Applicant's invention applied to improve the Spirometer are also applied in the instant application to improve the various types of medical apparatuses identified in the application.

There is a famous saying which states that "By three methods we may learn wisdom: First, by reflection, which is noblest; Second, by imitation, which is easiest; and third by experience, which is the bitterest." As shown above, Applicant has chosen to rely on the first and third methods with the development of his inventions. The second method, "imitation" is not a method employed by Applicant and with respect to the cited Mault '178 patent would not have been possible, given that Mault's patent did not issue until well after Applicant had filed his above mentioned applications, including the instant application currently under examination.

In summary, Applicant has spent the last 10 years working and reflecting on this new and novel means for helping patient recovery through usage his medical apparatuses, based on his own medical experiences discussed above, especially after having critical quadruple bypass surgery. It would be a shame to rob the world of the opportunity to benefit from this medical improvement, especially since it was learned the hard way by Applicant, namely through actual experience. Accordingly, Applicant respectfully requests that the instant invention of improving various medical apparatus be issued into a patent, not just because of his medical experiences, but because his invention "is" truly novel.